AUDIT REPORT FOR HUNGARY

NOVEMBER 15 THROUGH NOVMBER 30, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Hungary's meat inspection system November 15 through November 30, 2000. Six of eight establishments certified to export meat product to the United States were audited. All of these were slaughter and processing establishments.

The last on-site audit of Hungary's inspection system was conducted in February 2000. Six establishments 6, 7, 10, 24, 64, and 147 were onsite audited, and were acceptable. Inspection system monitoring and control records, and establishment system documents of establishments 5, 46, and 62 were also audited.

The following deficiencies were cited during the previous audit:

- 1. Use of inaccurate statistical process control criteria for evaluating *Escherichia coli* (*E. coli*) test results in establishment 6.
- 2. HACCP plans in establishments 6, 7, 10, 24, 64, and 147 did not adequately address analyses for hazards likely to occur including *Listeria monocytogenes* (not done) for ready to eat product. Critical control points (CCPs), monitoring frequency of critical limits, actions to correct or prevent recurrence of deviation from a critical limits, and on-going verification of HACCP plans were also not addressed adequately. Similar deficiencies were noted in establishments 5, 46, and 62 during documents audit.
- 3. Failure to implement zero tolerance policy in establishment 147.
- 4. Ineffective sanitation standards operating procedures (SSOPs) in establishments 6, 7, and 64.
- 5. Failure to meet performance standards for sanitation, facilities and equipment in establishment 6 and 7 for clogged/overflowing hand wash lavatories, and in established in establishment 64 (work boots carcass contact), and in establishments 6 and 64 (rodent and insect control), and establishment 64 (damaged/cracked edible product containers).
- 6. Residue analytical results were not signed and dated by the analyst and/or the supervisor.
- 7. Non-availability of compliance enforcement reports

The auditor verified that all of the above deficiencies had been corrected, except for lack of hazards analysis for *Listeria monocytogenes* for ready-to-eat product in all establishments audited. Establishments 64 and 147 were closed, and their compliance with the requirements could not be verified.

During January to October 31, 2000, Hungary exported 4,704,445 pounds of cured pork, and pasteurized canned hams and picnics to the United States. At the U.S. port of entry on reinspection 1,518 pounds were rejected for missing shipping marks.

PROTOCOL

The on-site review was conducted in four parts. One part involved visits with Hungarian national meat inspection officials at Budapest headquarters to discuss oversight programs and practices, including enforcement activities. The second part entailed on-site audit of six of establishments 5, 6, 7, 10, 24, and 62 of eight establishments certified for export to U.S. The records of two establishments 64 and 147 were not available. The establishments had been closed due to economic reasons. The third part was visits to and audit of records in the National Food Control Institute's Residue reference and analytical laboratory, reviewing feed stuff records in State Control Institute for Veterinary Biologicals, Drugs and Feedstuffs, and visit to and auditing of records in one of the 20 County Animal Health and Food Control Station's laboratories testing samples for the national residue and microbiological monitoring program including *Salmonella* species, *E. coli*. The fourth part included visit to a livestock farm to verify animal husbandry and proper use and monitoring/control of antibiotics, drugs, and other regulated chemicals or compounds, and a visit to a rendering facility to verify transportation and inedible/condemned product and dead animals control from being diverted to feed chain.

Hungary's inspection program's effectiveness determination focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation of Hazard Analysis and critical Control Point (HACCP) systems, and the *E. coli* testing program, and (5) enforcement controls, including the testing program for species identification.

Emphasis was placed on verification of information provided by Hungary's on the national residue control system in response to FSIS questionnaire on 'Residue Control and Testing Program, which included laboratory testing, intra- and inter-agency legislation and regulatory authority, and compliance enforcement.

During on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/ adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Adequate inspection controls were found to be in place in five (Ests. 6, 7, 24, and 62) of the six establishments audited. One (Est. 5) was recommended for re-review due to inadequate SSOPs control, inconsistent HACCP plans and their implementation, and lack of inspection coverage during second shift operations.

In all establishments visited sanitary procedures to re-condition incidentally dropped meat were not available; inedible or condemned product and dead carcasses were not denatured or decharacterized before off-premises shipment. In establishments 5, 10, 24 and 62 loose plastic strands were observed in plastic product containers.

In all establishments, *Listeria monocytogenes* as hazards likely to occur in ready-to-eat product was not analyzed and/or included in HACCP plans. In establishments 5 and 7, 11 positive *Listeria monocytogenes* samples were recorded in ready-to-eat product, and preventive or corrective measures taken were not documented.

Species identification monitoring was not being done in establishment 5 and 24, which supplied raw beef and pork to direct exporters to U.S.

Hungary's national residue control system met U.S. equivalency standards on sampling and analytical design, availability/application and use of drugs and other regulated chemicals or compounds, use of additives and medicaments in animal feeds, and control of prohibited compounds, and withdrawal period for restricted ingredients.

Entrance Meeting

An entrance meeting was held at the Hungary's Ministry of Agriculture and Regional Development's Department of Animal Health and Food Control headquarters on November 15, 2000, and was attended by Dr. Ágnes Horváth, Head Food Control department, Dr. Imre Rayda, Head National Food Investigating Institute, Dr. Sándor Tili, Head Export department, Dr. Veronica Oláh, Senior Veterinary Officer, National Food Investigation Institute, and Dr. Brigitta Eckhart, Veterinary Officer, Anila Health and Food Control department. FSIS auditors Drs. Hussain Magsi and M. Ghias Mughal, and Mr. F. Nemes, FAS/US Embassy. Discussions included:

- Audit itinerary and travel arrangements.
- Use of nutritional or geographic claim labels.
- SSOPs, HACCP, Escherichia coli (E. coli), Salmonella., and Listeria monocytogenes testing.
- National residue control program, and verification of Hungary's response to FSIS Questionnaire on national residue control program.
- FSIS policy on 'listing and delisting' of establishments.
- Compliance enforcement.

Hungary's inspection system officials stated that corrective measures had been initiated to prevent the recurrence of deficiencies noted during the previous FSIS audit in February 2000.

Headquarters Audit

There had been no organizational changes in Hungary's meat inspection systems. Some of the key official's changes made since last FSIS audit include:

Dr. Antal Nemeth - Chief Veterinary Officer (CVO),

Dr. Laura Herpay, Deputy CVO,

Dr. Ágnes Horváth, Head of Department of Food Control, and

Dr. Barnabas Sas, Executive Director, National Food Investigation Institute.

To gain an accurate overview of the effectiveness of inspection controls, FSIS auditor requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. requirements. The FSIS auditor (herein) called "the auditor" observed and evaluated the process.

The auditors conducted a review of the inspection system documents, which included:

- Organizational structure of Animal Health and Food Control Department.
- New initiatives and regulatory changes (Act, regulations, and policy).
- Internal audit/monthly supervisory reports.
- Food safety initiatives such as Sanitation standards and operating procedures (SSOPs), pathogen reduction (PR) for generic *E. coli* testing, *Salmonella* species, and *Listeria monocytogenes* testing, and Hazard analysis and critical control point (HACCP).
- Performance standards for sanitation, facilities, and equipment including water potability and insect and rodent control, etc.
- Slaughter and processing inspection procedures and standards including labels approval, boneless inspection, etc.
- Label approvals
- Epidemiology, and zoonotic trends in Hungary including control of products from livestock disease conditions.
- National residue control program.
- Livestock husbandry practices, including use of drugs and chemical and feed additives, and disease control.
- Compliance enforcement.

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by Hungary to export meat product to the United States were full-time or part-time employees receiving no remuneration directly from either industry or establishment personnel. All U.S.-certified establishments are provided continuous inspection, however in establishment 5 inspection coverage was not provided during the second shift.

In Hungary, there is an Animal Health and Food Control Station (Department) in each of 20 counties, and three veterinary institutes: Veterinary Diagnostic Central, National Food Investigating, and Veterinary Biologics, Drugs and Animal Foodstuffs. Animal Health and Food Control Department comprising of about 80 headquarters employees in Budapest is managed by Dr. Antal Nemeth, Chief Veterinary Officer. Dr. Ágnes Horváth, Head of Department of Food Control manages national food/meat inspection programs in 20 counties. District Veterinary Directors in each of the 20 Stations supervise Animal Health and Food Control activities.

Each county Station employs about 80 to 150 technical and administrative staff, and monitors and controls animal health, food hygiene, and laboratory functions. County government's two senior officers and field staff officers, for example 28 veterinary officers in Veszprem county, also provide livestock transportation certificates, verify withdrawal of drugs before slaughter, monitor and control additives and regulated drugs in animal feeds, and investigate violations of residue and other regulatory requirement requirements. Violations are investigated, and reported to police for legal action. Violators could be fined up to fr 1,000,000. There are no known cases of imprisonment.

Each of the 20 county governments, in addition to the meat inspection, operate a laboratory staffed with technicians and professionals – chemists, veterinarians, agricultural engineers, veterinary and food inspectors. These laboratories provide support for animal health, food safety, pathological, microbiological and antibiotic, and animal feed testing.

There are 27 Border Inspection points port of entry to control movement import and export of products and livestock. The country is bound by seven neighboring countries: Russia, Romania, Yugoslavia, Croatia, Slovenia, Austria and Slovakia, and is susceptible to foot and mouth disease and other exotic diseases.

The Central Veterinary Diagnostic Institute in Budapest coordinates animal health diagnostic and the residues control activities, and provides analytical confirmation and specialty support to 20 county laboratories.

Establishment Audits

Eight establishments 5, 6, 7, 10, 24, 62, 64, and 147 were certified to prepare and export meat products to the United States. Six of these were on-site audited. Establishments 64 and 147 were not operating due to economic reasons. Establishment 6, 7, 10, 24 and 62 were acceptable. Establishment 5 was determined marginally acceptable to be re-reviewed. With the exceptions described in the text, generally the inspection and establishment system controls were in place to prevent, detect and control contamination and adulteration of the product.

Laboratory Audits

The auditors visited National reference and analytical laboratory in Budapest, one of the 20 County animal health and food control laboratory in Megyei in Veszprem county, and four laboratories at the establishment premises. During the laboratory audits, emphasis was placed on

the application of procedures and standards that were equivalent to the U.S. requirements. Information about the following risk areas was also collected:

- 1. Government oversight of accredited, approved, and private laboratories.
- 2. Inter-laboratory quality assurance procedures, including sample handling.
- 3. Methodology.

The auditors visited County Animal Health and Food Central Laboratory in Veszprem. The laboratory was well equipped, and staffed with competent and qualified staff. It performs monitoring for microorganisms such as *E. coli, Salmonella* species, total plate counts, etc., food and meat products, food additives, animal feed stuffs and supplements, chlorinated hydrocarbons, trace elements, aflotoxins, mycotoxins, and microbiological and physico-chemical analysis of water.

The auditors visited State Control Institute for Veterinary Biologics, Drugs and Feeds in Budapest, and National residue Control Institute in Budapest. Discussions focused on responsibilities of the Institutes as related to drugs approval, monitoring use of biologics and medicaments, and control of additives in animal feeds by Country Animal Health and Food Control stations. The laboratory analytical results were made available for verification of the feed stuffs premixes, and feedstuffs. The auditors determined that official monitoring and control systems were in place and effective.

The auditors determined that effective controls were in place for sampling procedures, analytical procedures, quality assurance procedures, and review procedures. The analytical methods used were standard, or internationally validated. Prior deficiencies had been corrected.

Establishment Operations by Establishment Number

The following operations were being conducted in the six establishments:

Establishment 5 – Cattle and swine slaughter, cutting, boning, curing/drying/smoking product.

Establishment 6 – Cattle and swine slaughter, cut up, boning, curing/drying/smoking, non-shelf stable product canning, and edible rendering.

Establishment 7 – Cattle and swine slaughter, cut up, boning, curing/drying/smoking, and edible rendering.

Establishment 10 – Swine slaughter, cut up, boning, curing/drying, smoking, and non-shelf stable product.

Establishment 24 – Cattle and swine slaughter, cut up, and boning.

Establishment 62 – Swine slaughter cutup, boning, curing/drying/smoking, and non-shelf stable product canning.

SANITATION CONTROLS

Based on the on-site audits of establishments, Hungary's inspection system had controls in place for water potability records; chlorination procedures, back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest monitoring and control; temperature control; lighting; work space; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; and product storage.

Sanitation Standards Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

- The sanitary procedures for incidentally dropped meat in all establishments visited were not documented.
- In establishments 5, 10, 24 and 62, there were loose plastic strands in several product contact containers.
- Establishments 5 did not identify product contact equipment to be monitored during
 preoperational sanitation. There were inadequate monitoring and corrective actions to
 prevent recurrence of insanitary practices for condensation in carcass holding coolers, and for
 inadequate carcass dressing procedures for scraping, and cleaning before making opening cuts into
 the carcass for postmortem inspection.

ANIMAL DISEASE CONTROLS

Hungary's inspection system had controls in place to ensure adequate animal identification, antemortem and postmortem inspection procedures, carcass and parts disposition, and procedures for sanitary handling of product.

No outbreaks of animal diseases with public heath significance were reported since previous U.S. audit.

On November 27, 2000, the auditors also visited a private dairy and swine farm located in Herceghalom, Pest County. It was determined that livestock husbandry practices, and disease control program in Hungary was effective.

The auditor also determined that Hungary met following U.S. Animal and Plant Health Inspection Service's (APHIS) requirements.

RESIDUE CONTROLS

The auditors conducted an in-depth audit of Hungary's national residue control program to verify information provided by Hungarian Government in February 2000 in response to an FSIS questionnaire using a checklist on "Criteria for Assessing the Adequacy of the Residue Control Program for Meat, Poultry, and Egg Products". The criteria used for assessing the adequacy includes verification of Hungarian information on the background, organization and legal authority, residue plan, residue plan operations, monitoring laboratories, and compliance and enforcement.

Discussions were held with Hungarian key officials for animal Health and Food Control in Veszprim County, and National Food Investigation Institute, Budapest, and others in various branches of the government associated with national residue control and monitoring program. The discussions focused on (1) identifying and evaluating drugs, pesticides and other chemical compounds of concern by slaughter class and/or egg product, (2) capability to analyze compounds of concern reliability, (3) appropriate regulatory follow-up of reports of violative tissue residues in meat, poultry and egg product, (4) collection, analysis, and reporting of these activities, and (4) anticipated testing plan to analyze compounds of concern reliability for specific slaughter classes and/or egg products for a specified time period.

On November 23, 2000, the auditors accompanied with County Animal Health and Food Control also visited a private livestock farm located in Herceghalom, Pest County. The observations and records review indicated that sufficient controls existed for animal health, animal identification, medicament inventories, acquisition/use of veterinary drugs and supplemental feed additives, and withdrawal time before animal movement for slaughter.

It was determined that Hungarian National Residue Control Plan for 2000 was being followed, and was on schedule. The Hungarian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

The auditor determined that Hungary's residue control program, in general, was comparable with U.S. requirements.

SLAUGHTER/PROCESSING CONTROLS

The Hungarian inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem disposition; humane slaughter; postmortem inspection procedures; postmortem disposition; restricted product control; boneless meat inspection; ingredient identification; control of restricted ingredients; formulations; packaging materials; inspector monitoring; processing schedules; processing equipment and records; empty inspection and filling procedures; container closure examination; post-processing handling; processing defect action-plant; and processing control-inspection.

HACCP Implementation

Establishments approved to export meat products to the U.S. were required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instruments used accompanies this report (Attachment B).

The HACCP program was found to meet basic FSIS regulatory requirements. However, *Listeria monocytogenes* as hazard likely to occur was not determined in all establishments. In establishment 5, eight positive samples, and three positive samples in establishment 7 were recorded. It was stated that the adulterated product was destroyed, but no preventive action was initiated.

Testing for generic E. coli

Hungary has adopted the FSIS regulatory requirements for E. coli testing.

Establishments 5, 6, 7, 10, 24, and 62 were required to meet basic FSIS regulatory requirements for *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

No variations from those of U.S. requirements were noted.

ENFORCEMENT CONTROLS

<u>Inspection System Controls</u>

The establishment's system conducts boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product.

In establishments 10 and 62 both shift operations were covered by inspection service. However, inspection coverage, contrary to Hungarian and U.S. requirements, was not provided in establishment 5 during the second shift operations.

In establishment 5, the official inspectors did not monitor the implementation, and/or the effectiveness of SSOPs, and the night shift operations were not being provided with inspection coverage.

In all of the establishments visited the inedible/condemned product and dead on arrival carcasses were not being denatured/ decharacterized before off-premises shipping.

Testing for Salmonella species

Establishments 5, 6, 7, 10, 24, and 62 were required to meet the basic FSIS regulatory requirements for *Salmonella* species testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The *Salmonella* species-testing program was audited, and found to meet the FSIS determined equivalence. The inspection service collected samples. In case of positive case, product is identified, re-called if available, and confiscated for further action. Future shipments are withheld subject to laboratory analyses clearance. Investigation is conducted to determine root-cause(s) of product adulteration.

Testing for *Listeria monocytogenes*

One sample was collected from each month for ready to eat product in all ready-to-eat preparing products. However, documentation on corrective measures taken was not available. In establishment 5 eight samples, and in establishment 7 three samples were found positive. There was no established official policy or requirements specified for *Listeria* adulteration.

Analysis for hazard likely to occur was not conducted in all ready-to-eat product-preparing establishments.

Species Verification Testing

At the time of this audit, Hungary was not exempt from species verification-testing requirement, and testing was not being done. Monthly samples were collected from active U.S.-export establishments. However, samples were not collected in establishments 5, and 24.

Samples were not being collected from establishment 5 and 24, which prepared beef and pork, and supplied to direct exporters to U.S.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less frequently than one such visit per month, during any period when the establishment is engaged in producing products that could be used for exportation to the United States. Responsible supervisory officials were conducting monthly establishment audits.

Enforcement Activities

Each county Station's field staff officers, for example 28 veterinary officers in Veszprem county, provide livestock transportation certificates, verify withdrawal of drugs before slaughter, monitor and control additives and regulated drugs administration to the livestock and use in feed stuffs, monitor rendering facilities, and investigate violations of residue and other regulatory requirement. Violations are reported to police for legal action. Violators could be fined up to Fr 1,000,000. The compliance enforcement action pertaining to product confiscation, fines, and imprisonment are legislated. It was stated that actions are taken when laws are transgressed.

Hungarian government provided a copy of official compliance enforcement report. The latest FSIS Quarterly Regulation and Enforcement Report (April - June 2000) was presented to the meat inspection officials.

Two samples were in violation of sulfanomides in Est. 24 and one for zinc in Est. 6. It was stated that the two establishments were debarred to export to the United States. A sulfonamide violation case report (summary) in a monitoring sample from Est. 7 was also reviewed. Information was relayed to county animal health and food control officials to pursue investigation and legal action if warranted.

Exit Meeting

An exit meeting was conducted in Budapest on November 30, 2000, and was attended by Dr. Dr. Ágnes Horváth; Head Food Control department chaired the meeting. She stated that CVO and the Deputy CVO could not attend due to previous engagements with EU Commission officials. Other attendees were Dr. Imre Rayda, Head National Food Investigating Institute, Dr. Sándor Tili, Head Export department, Dr. Veronica Oláh, Senior Veterinary Officer, National Food Investigation Institute, and Dr. Brigitta Eckhart, Veterinary Officer, Animal Health and Food Control department. FSIS auditor Dr. Hussain Magsi, and M. Ghias Mughal, Branch Chief, FSIS International Audit Staff, and Mr. Paul Spencer-MacGregor, Agricultural Attaché, U.S. Embassy (stationed in Vienna, Austria), and Mr. Ference Nemes, FAS/U.S. Embassy, Budapest. FSIS auditor discussed the findings and observations made during the audit.

It was stated that:

- 1. SSOPs, and performance standards for sanitation, facilities and equipment deficiencies. Establishment 5 had presented an action plan to rectify all the deficiencies, and was being followed to correct all deficiencies noted. A copy of the plan was presented for review.
- 2. Inspection service would detail an official inspector to cover second shift operations in establishment 5, until a new permanent employee can be hired.
- 3. In-plant inspector and county officials would be required to perform daily monitoring and verification of implementation and effectiveness of SSOPs and performance standards for sanitation, facilities and equipment.
- 4. Inspection service would evaluate and verify written plans for hazards likely to occur for *Listeria monocytogenes* for corrective and preventive measures.
- 5. Official guidelines would be issued on how to deal with situations when positive cases of *Listeria* were recorded.
- 6. Official guidelines would be issued on performance standards for procedures for sanitary handling of incidentally contaminated meats.
- 7. For species identification sampling and analysis, a mandatory legislation is being drafted, and would be in place next year.
- 8. Legislation is being developed for high and low risk condemned or inedible materials, which would also comply with U.S. requirements.

It was stated that the inspection had initiated corrective action immediately to prevent and control deficiencies noted during this review.

CONCLUSION

The overall establishment system was determined equivalent to that FSIS requires in domestic establishments. However, *Listeria* as a hazard likely to occur was not analyzed, even when several samples were positive. The SSOPs requirements were met in most establishments but on-going verification of the effectiveness of SSOPs was not being done in the establishments. The species identification analysis was not being done in establishments preparing beef and pork product. The corrective and preventive measures for *Listeria* adulteration were inadequate. The transportation controls and denaturing of condemned/ inedible or dead animals were inadequate. Continuous inspection coverage was not being provided in one of the establishment during second shifts operations. Hungary's national residue control program was determined to meet U.S. requirements.

(signed)Hussain Magsi, DVM, MS Hussain Magsi, DVM, MS International Audit Staff Officer

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for Salmonella testing
- E. Laboratory audits forms.
- F. Individual Foreign Establishment Audit Forms.
- G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available).
- I. FSIS Response(s) to Foreign Country Comments (when it becomes available).

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written SSOP program.
- 2. The procedure addresses pre-operational sanitation.
- 3. The procedure addresses operational sanitation.
- 4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
- 5. The procedure indicates the frequency of the tasks.
- 6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
- 7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
- 8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

| Est. No. | 1.Written program addressed | 2. Pre-op sanitation addressed | 3. Operational sanitation addressed | 4. Contact surfaces addressed | 5. Frequency addressed | 6.Responsible individual Identified | 7.Documenta- tion done daily | 8. Dated and signed |
|-------------|-----------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|------------------------|-------------------------------------|------------------------------------|---------------------|
| 5 | √ | √ | V | No | V | V | V | V |
| 6 | | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ |
| 7 | | $\sqrt{}$ | V | V | $\sqrt{}$ | V | $\sqrt{}$ | $\sqrt{}$ |
| 10 | | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ |
| 24 | V | V | V | V | V | V | V | V |
| 62 | | $\sqrt{}$ | V | V | $\sqrt{}$ | V | $\sqrt{}$ | $\sqrt{}$ |

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. The establishment has a flow chart that describes the process steps and product flow.
- 2. The establishment had conducted a hazard analysis.
- 3. The analysis includes food safety hazards likely to occur.
- 4. The analysis includes the intended use of or the consumers of the finished product(s).
- 5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
- 6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
- 1. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
- 2. The plan describes corrective actions taken when a critical limit is exceeded.
- 9. The HACCP plan was validated using multiple monitoring results.
- 10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
- 11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
- 12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

| Est. | 1.Fl | 2.Hazard | 3. All | 4. Use | 5. Plan | 6. CCPs | 7.Monit. | 8.Correc- | 9. Plan | 10. | 11. | 12. |
|------|--------------|--------------|---------|-----------|--------------|---------|--------------|--------------|--------------|--------------|-----------|-----------|
| No | ow | analysis | hazards | and | for | for all | critical | tive | validated | Adeq. | Adeq. | dated |
| | diag | done | identi- | users | each | hazards | limits, and | actions | | Verific. | Docum. | and |
| | ram | | fied | included. | hazard | | freq. | described | | Proc. | | Signed |
| | | | | | | | specified | | | | | |
| 5 | | \checkmark | | | \checkmark | *No | \checkmark | \checkmark | \checkmark | \checkmark | $\sqrt{}$ | $\sqrt{}$ |
| 6 | \checkmark | | | | $\sqrt{}$ | *No | $\sqrt{}$ | $\sqrt{}$ | | $\sqrt{}$ | | $\sqrt{}$ |
| 7 | | | | | | *No | | | | | | |
| 10 | | | | | | *No | | | | V | V | V |
| 24 | | | | | | NA | | $\sqrt{}$ | | $\sqrt{}$ | | |
| 62 | | V | V | V | | *No | V | V | V | V | V | $\sqrt{}$ |

^{*} Listeria monocytogenes as hazard likely to occur was not analyzed. In establishment 5 and 7 there were 8 and 3 positive samples respectively, but no hazard analysis or reassessment was done.

Data collection instruments for E. coli testing

Following information was collected.

- 1. The establishment has a written procedure for testing for generic *E. coli*.
- 2. The procedure designates the employee(s) responsible to collect the samples.
- 3. The procedure designates the establishment location for sample collecting.
- 4. The sample collection is done on the predominant species being slaughtered.
- 5. The sampling is done at the frequency specified in the procedure.
- 6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
- 7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
- 8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
- 9. The results of the tests are being recorded on a process control chart showing the most recent test results.
- 10. The test results are being maintained for at least 12 months.

The results of these evaluations were as follows:

| Est. | 1. Written | 2. Sample | 3.Sampling | 4.Predomi- | 5.Sampling | 6.Proper | 7.Sampling | 8. Using | 9. Chart or | 10. Results |
|------|------------|------------|------------|------------|-------------|-----------|------------|-----------|-------------|--------------|
| No. | procedure | collector | location | nant spp. | at required | site or | is random | AOAC | graph of | are kept at |
| | | designated | given | sampled | frequency | method | | method | results | least 1 yr |
| 5 | $\sqrt{}$ | | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | | $\sqrt{}$ | | |
| 6 | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | \checkmark |
| 7 | | $\sqrt{}$ | $\sqrt{}$ | V | √ | $\sqrt{}$ | V | √ | √ | √ |
| 10 | V | $\sqrt{}$ | $\sqrt{}$ | V | √ | $\sqrt{}$ | V | V | √ | √ |
| 24 | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | V | √ | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | √ | √ |
| 62 | V | | $\sqrt{}$ | V | $\sqrt{}$ | | $\sqrt{}$ | V | | $\sqrt{}$ |

Data Collection instruments for Salmonella spp. Testing

All slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* species testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. Salmonella testing is being done in this establishment.
- 2. Carcasses are being sampled.
- 3. Ground product is being sampled.
- 4. The samples are being taken randomly.
- 5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
- 6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

| Est. No. | 1. Testing as | 2. Carcasses | sses 3. Ground 4. Sar | | 5. Proper site | 7.Violative | |
|----------|---------------|--------------|-----------------------|--------------|----------------|-------------|--|
| | required | are sampled | product is | taken | and/or proper | Est. stop | |
| | | | sampled | randomly | production | operations | |
| 5 | \checkmark | \checkmark | NA | \checkmark | \checkmark | $\sqrt{}$ | |
| 6 | $\sqrt{}$ | $\sqrt{}$ | NA | $\sqrt{}$ | $\sqrt{}$ | V | |
| 7 | V | V | NA | V | √ | V | |
| 10 | V | V | NA | V | V | V | |
| 24 | V | V | NA | V | V | V | |
| 62 | $\sqrt{}$ | V | NA | | √ | V | |